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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,076	08/30/2001	Martin Schurenberg	B0004/7087	7692
21127	7590	01/20/2004	EXAMINER	
KUDIRKA & JOBSE, LLP ONE STATE STREET SUITE 800 BOSTON, MA 02109			GAKH, YELENA G	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 01/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/943,076

Applicant(s)

SCHURENBERG ET AL.

Examiner

Yelena G. Gakh, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 10-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 01/16/02.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Election filed on 10/24/03 is acknowledged. Claims 1-18 are pending in the application, from which claims 10-18 are withdrawn from the consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a plate with "hydrophilic anchor regions on an otherwise hydrophobic or lyophobic surface". Such description does not leave any space for "areas with affinity adsorbents", unless they are a part of hydrophilic or hydrophobic area. Since the language of the claim is not definite, the examiner considers "areas with affinity adsorbents" a part of hydrophilic anchor regions.

In claim 3 it is not clear, what is "the basic quadratic array of 9 millimeters for individual microwells", or "a finer array arising from that by division by an integer number"? These expressions do not make sense and need to be clarified.

In claim 6 it is not clear, how affinity adsorbents can be used for screening of specific groups of biosubstances. What does the word "screening" mean here?

Claim 7 recites, "hydrophilic anchor areas are accompanied by affinity areas", which does not imply and definite structural relation between the hydrophilic anchor areas and affinity areas and renders the claim indefinite.

Claim 8 recites a relative term "small", which renders it indefinite.

Claim 9 recites the number of anchor area being from 3 to 9. What number is meant here? The number of the anchor area on the strip? The number of anchor areas for each hydrophilic area? The claim of the language is unclear.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 1, 3-6 and 9** are rejected under 35 U.S.C. 102(e) as being anticipated by Beecher et al. (US 2003/0106997 A1, priority filing date 04/29/1999).

Beecher discloses a sample support plate with a flat surface for MALDI (matrix-assisted laser desorption and ionization) analysis, comprising a flat substrate, which “can be in any shape as long as allows the probe (support plate) to be removably insertable into a mass spectrometer” (page 3, [0043]), a strip in particular (Fig. 1); the substrate is made of amphiphilic (partially hydrophilic) polymers, such as polyacetylenes, polyanilines, polythiophenes, etc. (page 3, [0042]). The substrate is covered with highly hydrophobic film with a water contact angle between 120° and 180° with openings exposing amphiphilic (hydrophilic) substrate (page 1, [0012]), with the exposed substrate areas additionally having “adsorbents attached that will selectively bind analytes. The adsorbents can be highly specific for an analyte, such as antibodies, or they can be relatively unspecific, such as anion or cation exchange resins” (page 3, [0045]). The latter usually contain alkane chains, see e.g. Lecture 31, “Protein purification”. Figure 1 shows the sample support with eight such affinity areas.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Beecher.

Although Beecher does not specifically disclose affinity areas of different biospecificity, it would have been obvious for anyone of ordinary skill in the art to slightly modify Beecher's plate by introducing anchor areas of different biospecificity, because it obviously increases efficiency of the plate in using it for mixtures of different analytes.

10. **Claims 1 and 3-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockman et al. (Anal. Chem., 1995) or Hutchens et al. (US 5,719,060) in view of Willard et al. (US 5,831,184) or Turner et al. (US 5,958,345).

Brockman and Hutchens disclose a MALDI support plate, the flat surface of which is modified with affinity regions, which allow direct affinity separations on MALDI plate: "probe affinity MS directly couples the high selectivity of immobilized affinity chromatography with the sensitivity of MALDI-MS" (Brockman, Abstract).

Brockman and Hutchens do not specifically discuss hydrophilic anchor regions on hydrophobic surface with the regions corresponding microwells of a standard microwell plate, although the surface of MALDI plate is hydrophobic and affinity regions can be considered hydrophilic.

Willard and Turner disclose improved support plate for analysis of analyte on the plate with hydrophilic anchor regions corresponding the microwells of the standard microwell plate on otherwise hydrophobic substrate (Abstracts, Figures). The plate is designed for positioning small amount of the sample in a precise location for chemical analysis. The hydrophobic surface "prevents the sample from spreading out beyond the hydrophilic portion, thereby ensuring that the chemical to be analyzed will be properly positioned when the liquid evaporated" (Turner, col. 1, lines 12-17).

It would have been obvious for anyone of ordinary skill in the art to improve Brockman's or Hutchens' plate by placing hydrophilic anchor area in form of arrays corresponding to arrays of microwell plates on the hydrophobic support surface in addition to affinity regions, because Brockman and Hutchens well recognize the problem of placing a small amount of the analyte at a predetermined location: "any improvement in the prior art procedure which would make it possible to 1) use much less analyte, 2) to locate the analyte or multiple analytes on the probe tip or surface in a predetermined location, 3) to perform repeated analyses of the same aliquot of analyte (e.g., before and after one or more chemical and or enzymatic reactions), and 4) to conduct the test in a more quantitative manner, would be highly advantageous in many clinical areas" (Hutchens, col. 2, lines 5-13). This problem is solved by Willard's and Turner's invention. It would have been obvious for anyone of ordinary skill in the art to make such support of any shape convenient for MALDI analysis, including a strip, with affinity areas of different biospecificity for analysis of mixtures of analytes.

Allowable Subject Matter

11. **Claim 2** would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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The following is a statement of reasons for the indication of allowable subject matter:

The prior art cited above does not teach or fairly suggest a support plate for MALDI analysis of biomolecules with areas of affinity adsorbents for biomolecules forming rings around the hydrophilic anchor regions and surrounded in turn by the hydrophobic layer of the sample support plate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1700.

Yelena G. Gakh, Ph.D.
1/9/04

